IX. 510(k) Summary

SUBMITTER: DePuy Spine
325 Paramount Drive
Raynham, MA 02780

SEP 11 2006

CONTACT PERSON: Mary Gray

DATE PREPARED: July 31, 2006

CLASSIFICATION NAME: Appliance, Fixation, Spinal Interlaminal
Orthosis, Spinal Pedicle Fixation

PROPRIETARY NAME: SFX Snap-Fit Cross Connector

PREDICATE DEVICES: MOSS MIAMI Spinal System Transverse Connector (K955348).

DEVICE DESCRIPTION: The SFX Connector is designed to transversely connect two rods used in spinal instrumentation constructs. The connector minimizes the torsional forces on the construct, thus reducing the micromotion and the probability of the construct shifting after placement. It is designed to accommodate the 5.5mm spinal rods of the EXPEDIUM Spine System.

INTENDED USE: The SFX Snap-Fit Cross Connectors are designed to transversely connect two rods used in spinal instrumentation constructs. The SFX Snap-Fit Cross Connector devices are intended for use with components of the commercially available EXPEDIUM™ 5.5mm Spine System.

The uses of the legally marketed EXPEDIUM™ 5.5mm Spine System are as follows:

The EXPEDIUM™ Spine System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.

MATERIALS: Manufactured from ASTM F-136 implant grade titanium alloy.

PERFORMANCE DATA:

Performance data were submitted to characterize the SFX Snap-Fit Cross Connector.

IX. 510(k) Summary

SUBMITTER:	DePuy Spine 325 Paramount Drive Raynham, MA 02780
CONTACT PERSON:	Mary Gray
DATE PREPARED:	July 31, 2006
CLASSIFICATION NAME:	Appliance, Fixation, Spinal Interlaminal Orthosis, Spinal Pedicle Fixation
PROPRIETARY NAME:	SFX Snap-Fit Cross Connector
PREDICATE DEVICES:	MOSS MIAMI Spinal System Transverse Connector (K955348).
DEVICE DESCRIPTION:	The SFX Connector is designed to transversely connect two rods used in spinal instrumentation constructs. The connector minimizes the torsional forces on the construct, thus reducing the micromotion and the probability of the construct shifting after placement. It is designed to accommodate the 5.5mm spinal rods of the VIPER System.
INTENDED USE:	The SFX Snap-Fit Cross Connectors are designed to transversely connect two rods used in spinal instrumentation constructs. The SFX Snap-Fit Cross Connector devices are intended for use with components of the commercially available VIPER™ System. The uses of the legally marketed VIPER™ System are as follows: The VIPER Spine System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients. When used in a percutaneous, posterior approach with MIS instrumentation, the VIPER System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc

	confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.
MATERIALS:	Manufactured from ASTM F-136 implant grade titanium alloy.
PERFORMANCE DATA:	Performance data were submitted to characterize the SFX Snap-Fit Cross Connector.

IX. 510(k) Summary

SUBMITTER:	DePuy Spine 325 Paramount Drive Raynham, MA 02780
CONTACT PERSON:	Mary Gray
DATE PREPARED:	July 31, 2006
CLASSIFICATION NAME:	Appliance, Fixation, Spinal Interlaminal Orthosis, Spinal Pedicle Fixation
PROPRIETARY NAME:	SFX Snap-Fit Cross Connector
PREDICATE DEVICES:	MOSS MIAMI Spinal System Transverse Connector (K955348).
DEVICE DESCRIPTION:	The SFX Connector is designed to transversely connect two rods used in spinal instrumentation constructs. The connector minimizes the torsional forces on the construct, thus reducing the micromotion and the probability of the construct shifting after placement. It is designed to accommodate the 6.35mm spinal rods of the VSP Spine System.
INTENDED USE:	The SFX Snap-Fit Cross Connectors are designed to transversely connect two rods used in spinal instrumentation constructs. The SFX Snap-Fit Cross Connector devices are intended for use with components of the commercially available VSP® 6.35mm Spine System. The uses of the legally marketed VSP® Spine System are as follows: The VSP System is indicated for degenerative spondylolisthesis, in skeletally mature patients, with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). Levels of fixation are for the thoracic, lumbar and sacral spine. The VSP® Spine System is also indicated for pedicle screw fixation for severe spondylolisthesis (Grade 3 and 4) at L5-S1, in skeletally mature patients, when autogeous bone graft is used, when affixed to the posterior lumbosacral spin, and intended to be removed after solid fusion is attained. Levels of fixation are from L3-S1.

MATERIALS:	Manufactured from ASTM F-136 implant grade titanium alloy.
PERFORMANCE DATA:	Performance data were submitted to characterize the SFX Snap-Fit Cross Connector.

IX. 510(k) Summary

SUBMITTER:	DePuy Spine 325 Paramount Drive Raynham, MA 02780
CONTACT PERSON:	Mary Gray
DATE PREPARED:	July 31, 2006
CLASSIFICATION NAME:	Appliance, Fixation, Spinal Interlaminal Orthosis, Spinal Pedicle Fixation
PROPRIETARY NAME:	SFX Snap-Fit Cross Connector
PREDICATE DEVICES:	MOSS MIAMI Spinal System Transverse Connector (K955348).
DEVICE DESCRIPTION:	The SFX Connector is designed to transversely connect two rods used in spinal instrumentation constructs. The connector minimizes the torsional forces on the construct, thus reducing the micromotion and the probability of the construct shifting after placement. It is designed to accommodate the 6.35mm spinal rods of the ISOLA Spine System.
INTENDED USE:	The SFX Snap-Fit Cross Connectors are designed to transversely connect two rods used in spinal instrumentation constructs. The SFX Snap-Fit Cross Connector devices are intended for use with components of the commercially available ISOLA® 6.35mm Spine System. The uses of the legally marketed ISOLA 6.35mm Spine System are as follows: The ISOLA Spine Systems is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The ISOLA Spine Systems is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having

implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The ISOLA Spine Systems is also a hook and sacral/iliac screw fixation system of the noncervical spine indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudarthrosis).

The ISOLA Spinal System when used with pedicle screws is indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies). Levels of fixation are for the thoracic, lumbar and sacral spine.

MATERIALS: Manufactured from ASTM F-136 implant grade titanium alloy.

PERFORMANCE DATA: Performance data were submitted to characterize the SFX Snap-Fit Cross Connector.

IX. 510(k) Summary

SUBMITTER:	DePuy Spine 325 Paramount Drive Raynham, MA 02780
CONTACT PERSON:	Mary Gray
DATE PREPARED:	July 31, 2006
CLASSIFICATION NAME:	Appliance, Fixation, Spinal Interlaminal Orthosis, Spinal Pedicle Fixation
PROPRIETARY NAME:	SFX Snap-Fit Cross Connector
PREDICATE DEVICES:	MOSS MIAMI Spinal System Transverse Connector (K955348).
DEVICE DESCRIPTION:	The SFX Connector is designed to transversely connect two rods used in spinal instrumentation constructs. The connector minimizes the torsional forces on the construct, thus reducing the micromotion and the probability of the construct shifting after placement. It is designed to accommodate the 5.5mm and 6.35mm spinal rods of the MOSS MIAMI Spine System.
INTENDED USE:	The SFX Snap-Fit Cross Connectors are designed to transversely connect two rods used in spinal instrumentation constructs. The SFX Snap-Fit Cross Connector devices are intended for use with components of the commercially available MOSS® MIAMI 5.5mm and 6.35mm Spine Systems. The uses of the legally marketed MOSS MIAMI 5.5mm and 6.35mm Spine Systems are as follows: When used as a posterior, noncervical hook, and/or sacral/iliac screw fixation system, or as an anterior, thoracic/lumbar screw fixation system, the MOSS MIAMI Spinal System is intended to treat scoliosis, kyphosis and lordosis, fracture, loss of stability due to tumor, spinal stenosis, spondylolisthesis, a previously failed fusion surgery or degenerative disc disease (i.e., discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies). When used as a pedicle screw fixation system of the noncervical spine in skeletally mature patients, the MOSS MIAMI Spinal System is indicated for degenerative spondylolisthesis with objective evidence of neurologic

impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudoarthrosis).

The MOSS MIAMI Spine Systems is also indicated for pedicle screw fixation in skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebral joint, having fusions with autogenous bone graft, with the device fixed or attached to the lumbar and sacral spine (levels of pedicle screw fixation are L3-S1) and for whom the device system is intended to be removed after solid fusion is attained.

MATERIALS: Manufactured from ASTM F-136 implant grade titanium alloy.

PERFORMANCE DATA: Performance data were submitted to characterize the SFX Snap-Fit Cross Connector.

IX. 510(k) Summary

SUBMITTER:	DePuy Spine 325 Paramount Drive Raynham, MA 02780
CONTACT PERSON:	Mary Gray
DATE PREPARED:	July 31, 2006
CLASSIFICATION NAME:	Appliance, Fixation, Spinal Interlaminal Orthosis, Spinal Pedicle Fixation
PROPRIETARY NAME:	SFX Snap-Fit Cross Connector
PREDICATE DEVICES:	MOSS MIAMI Spinal System Transverse Connector (K955348).
DEVICE DESCRIPTION:	The SFX Connector is designed to transversely connect two rods used in spinal instrumentation constructs. The connector minimizes the torsional forces on the construct, thus reducing the micromotion and the probability of the construct shifting after placement. It is designed to accommodate the 5.5mm and 6.35mm spinal rods of the MONARCH Spine System.
INTENDED USE:	The SFX Snap-Fit Cross Connectors are designed to transversely connect two rods used in spinal instrumentation constructs. The SFX Snap-Fit Cross Connector devices are intended for use with components of the commercially available MONARCH® 5.5mm and 6.35mm Spine System. The uses of the legally marketed MONARCH 5.5mm and 6.35mm Spine System are as follows: The MONARCH Spine Systems is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The MONARCH Spine Systems is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature

patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The MONARCH Spine Systems is also a hook and sacral/iliac screw fixation system of the noncervical spine indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudarthrosis).

The MONARCH Spine System when used with pedicle screws is indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies). Levels of fixation are for the thoracic, lumbar and sacral spine.

MATERIALS: Manufactured from ASTM F-136 implant grade titanium alloy.

PERFORMANCE DATA: Performance data were submitted to characterize the SFX Snap-Fit Cross Connector.

IX. 510(k) Summary

SUBMITTER:	DePuy Spine 325 Paramount Drive Raynham, MA 02780
CONTACT PERSON:	Mary Gray
DATE PREPARED:	July 31, 2006
CLASSIFICATION NAME:	Appliance, Fixation, Spinal Interlaminal Orthosis, Spinal Pedicle Fixation
PROPRIETARY NAME:	SFX Snap-Fit Cross Connector
PREDICATE DEVICES:	MOSS MIAMI Spinal System Transverse Connector (K955348).
DEVICE DESCRIPTION:	The SFX Connector is designed to transversely connect two rods used in spinal instrumentation constructs. The connector minimizes the torsional forces on the construct, thus reducing the micromotion and the probability of the construct shifting after placement. It is designed to accommodate the 6.35mm spinal rods of the TIMX Spine System.
INTENDED USE:	The SFX Snap-Fit Cross Connectors are designed to transversely connect two rods used in spinal instrumentation constructs. The SFX Snap-Fit Cross Connector devices are intended for use with components of the commercially available TIMX® 6.35mm Spine System. The uses of the legally marketed TIMX Spine System are as follows: The TIMX Spine Systems is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The TIMX Spine Systems is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to

sacrum) with removal of the implants after the attainment of a solid fusion.

The TIMX Spine Systems is also a hook and sacral/iliac screw fixation system of the noncervical spine indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudarthrosis).

MATERIALS: Manufactured from ASTM F-136 implant grade titanium alloy.

PERFORMANCE DATA: Performance data were submitted to characterize the SFX Snap-Fit Cross Connector.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 11 2006

DePuy Spine
% Mr. Mary Gray
Senior RA Associate
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K062196
Trade/Device Name: SFX Snap-Fit Cross Connector
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle Screw Spinal Fixation
Regulatory Class: Class II
Product Code: MNH, MNI, KWP
Dated: July 31, 2006
Received: August 1, 2006

Dear Ms. Gray:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276- 0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

III. Indications for Use

510(k) Number (if known): _____

Device Name: SFX Snap-Fit Cross Connector

Indications For Use:

The SFX Snap-Fit Cross Connectors are designed to transversely connect two rods used in spinal instrumentation constructs. The SFX Snap-Fit Cross Connector devices are intended for use with components of the commercially available VIPER™ System.

The uses of the legally marketed VIPER™ System are as follows:

The VIPER Spine System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.

When used in a percutaneous, posterior approach with MIS instrumentation, the VIPER System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.

Prescription Use: _____X_____ OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buell MD

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062196

III. Indications for Use

510(k) Number (if known): _____

Device Name: SFX Snap-Fit Cross Connector

Indications For Use:

The SFX Snap-Fit Cross Connectors are designed to transversely connect two rods used in spinal instrumentation constructs. The SFX Snap-Fit Cross Connector devices are intended for use with components of the commercially available VSP® 6.35mm Spine System.

The uses of the legally marketed VSP® Spine System are as follows:

The VSP System is indicated for degenerative spondylolisthesis, in skeletally mature patients, with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). Levels of fixation are for the thoracic, lumbar and sacral spine.

The VSP® Spine System is also indicated for pedicle screw fixation for severe spondylolisthesis (Grade 3 and 4) at L5-S1, in skeletally mature patients, when autogeous bone graft is used, when affixed to the posterior lumbosacral spin, and intended to be removed after solid fusion is attained. Levels of fixation are from L3-S1.

Prescription Use: _____X_____ OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bucher for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062196

III. Indications for Use

510(k) Number (if known): _____

Device Name: SFX Snap-Fit Cross Connector

Indications For Use:

The SFX Snap-Fit Cross Connectors are designed to transversely connect two rods used in spinal instrumentation constructs. The SFX Snap-Fit Cross Connector devices are intended for use with components of the commercially available ISOLA® 6.35mm Spine System.

The uses of the legally marketed ISOLA 6.35mm Spine System are as follows:

The ISOLA Spine Systems is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

The ISOLA Spine Systems is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The ISOLA Spine Systems is also a hook and sacral/iliac screw fixation system of the noncervical spine indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudarthrosis).

The ISOLA Spinal System when used with pedicle screws is indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies). Levels of fixation are for the thoracic, lumbar and sacral spine.

Prescription Use: _____X_____ OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buch MD

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062196

III. Indications for Use

510(k) Number (if known): _____

Device Name: SFX Snap-Fit Cross Connector

Indications For Use:

The SFX Snap-Fit Cross Connectors are designed to transversely connect two rods used in spinal instrumentation constructs. The SFX Snap-Fit Cross Connector devices are intended for use with components of the commercially available MOSS® MIAMI 5.5mm and 6.35mm Spine Systems.

The uses of the legally marketed MOSS MIAMI 5.5mm and 6.35mm Spine Systems are as follows:

When used as a posterior, noncervical hook, and/or sacral/iliac screw fixation system, or as an anterior, thoracic/lumbar screw fixation system, the MOSS MIAMI Spinal System is intended to treat scoliosis, kyphosis and lordosis, fracture, loss of stability due to tumor, spinal stenosis, spondylolisthesis, a previously failed fusion surgery or degenerative disc disease (i.e., discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies).

When used as a pedicle screw fixation system of the noncervical spine in skeletally mature patients, the MOSS MIAMI Spinal System is indicated for degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudoarthrosis).

The MOSS MIAMI Spine Systems is also indicated for pedicle screw fixation in skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebral joint, having fusions with autogenous bone graft, with the device fixed or attached to the lumbar and sacral spine (levels of pedicle screw fixation are L3-S1) and for whom the device system is intended to be removed after solid fusion is attained.

Prescription Use: _____X_____ OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062196

III. Indications for Use

510(k) Number (if known): _____

Device Name: SFX Snap-Fit Cross Connector

Indications For Use:

The SFX Snap-Fit Cross Connectors are designed to transversely connect two rods used in spinal instrumentation constructs. The SFX Snap-Fit Cross Connector devices are intended for use with components of the commercially available MONARCH® 5.5mm and 6.35mm Spine Systems.

The uses of the legally marketed MONARCH 5.5mm and 6.35mm Spine Systems are as follows:

The MONARCH Spine Systems is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

The MONARCH Spine Systems is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The MONARCH Spine Systems is also a hook and sacral/iliac screw fixation system of the noncervical spine indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudarthrosis).

The MONARCH Spine System when used with pedicle screws is indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies). Levels of fixation are for the thoracic, lumbar and sacral spine.

Prescription Use: _____X_____ OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062196

III. Indications for Use

510(k) Number (if known): _____

Device Name: SFX Snap-Fit Cross Connector

Indications For Use:

The SFX Snap-Fit Cross Connectors are designed to transversely connect two rods used in spinal instrumentation constructs. The SFX Snap-Fit Cross Connector devices are intended for use with components of the commercially available TIMX® 6.35mm Spine System.

The uses of the legally marketed TIMX Spine System are as follows:

The TIMX Spine Systems is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

The TIMX Spine Systems is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The TIMX Spine Systems is also a hook and sacral/iliac screw fixation system of the noncervical spine indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudarthrosis).

Prescription Use: _____X_____ OR Over-The-Counter Use: _____

(Per 21 CFR 801.109)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bruckup

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

III. Indications for Use

510(k) Number (if known): K062196

Device Name: SFX Snap-Fit Cross Connector

Indications For Use:

The SFX Snap-Fit Cross Connectors are designed to transversely connect two rods used in spinal instrumentation constructs. The SFX Snap-Fit Cross Connector devices are intended for use with components of the commercially available EXPEDIUM™ 5.5mm Spine System.

The uses of the legally marketed EXPEDIUM™ 5.5mm Spine System are as follows:

The EXPEDIUM™ Spine System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.

Prescription Use: X OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K062196